K073133

510(k) Summary

The following information is provided following the format of 21 CFR 807.92 for the Interstitial Needles.

Submitter: Varian Medical Systems
3100 Hansen Way M/S E-110
Palo Alto, CA 94304-1129
Contact Name: Ms. Vy Tran
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NOV 16 2007

Date summary was prepared: October 31st, 2007

Name of the Device: **Varian Interstitial Needles**
Trade/Proprietary Name: Varian Interstitial Needles
Common or Usual Name: Varian Interstitial Needles
Classification Name: System, Applicator, Radionuclide, Remote – Controlled
21 CFR 892.5700
Class II
Product Code: JAQ

Predicate Devices to claim substantial equivalence:
K952913 – Applicators for Varian VariSource Remote High Dose Rate Afterloader

AL13103000	18 Gauge Stainless Steel Needle, 100mm
AL13103001	18 Gauge Stainless Steel Needle, 150mm
AL13103002	18 Gauge Stainless Steel Needle, 200mm
AL13104000	20 Gauge Stainless Steel Needle, 100mm
AL13104001	20 Gauge Stainless Steel Needle, 150mm
AL13104002	20 Gauge Stainless Steel Needle, 200mm
AL13105000	21 Gauge Stainless Steel Needle, 100mm
AL13105001	21 Gauge Stainless Steel Needle, 150mm
AL13105002	21 Gauge Stainless Steel Needle, 200mm
AL13107000	Needle Cap Aluminum
AL13108000	Obturator Cap Aluminum

Description of the Device:
The device is a family of closed-ended, interstitial needles and associated obturators to be used in conjunction with a high dose rate (HDR) brachytherapy afterloading device. The needles are available in either 17 gauge O.D. or 18 gauge O.D. and in lengths of 113mm, 200mm, 250mm, and 320mm. The associated obturators are inserted into needles to stiffen the needles during implantation of the needles into the patient and to stiffen the needles between radiation therapy fractions. The obturators are available in lengths of 113mm, 200mm, 250mm, and 320mm.
The needles are provided unsterile with instructions for steam sterilization and have been qualified for 25 uses. The obturators are provided unsterile with instructions for steam sterilization and have been qualified for 100 uses.

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Intended Use Statement:
The Varian Remote High Dose Rate Afterloader system, including the applicators and accessories included in this notification, is a device intended to be used by properly trained and licensed medical personnel to provide radiation brachytherapy with a high specific activity radioisotope source to reduce the exposure times required to achieve a prescribed dose. Remote operation of the Afterloader eliminates the necessity of hand placement of radioactive sources on or within the body of a patient. The radioactive source is Iridium-192, encapsulated in the end of a wire stored in the Afterloader and mechanically driven from it to a precisely described position for a specified dwell time during treatment. Between treatments the wire is retracted into the Afterloader so that the source end resides in a tungsten-shielded safe to limit personnel exposures to an acceptable, safe level. The Afterloader contains a radiation detector which signals whenever the source is not in the safe.

Indications for Use Statement:
The Interstitial Needles are used with Varian High Dose Rate Afterloaders.

Summary of the Technological Characteristics:
The Substantial Equivalence Comparison Chart provides a comparison of the technological characteristics to those of the predicate device. The chart is located in Tab 7 of the submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 16 2007

Ms. Vy Tran
Senior Director, Corporate Regulatory Affairs
Varian Medical Systems, Inc.
3100 Hansen Way
PALO ALTO CA 94304

Re: K073133
Trade/Device Name: Interstitial Needles
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radio-nuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: November 5, 2007
Received: November 7, 2007

Dear Ms. Tran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073133

Device Name: Interstitial Needles

Indications for Use:

The Interstitial Needles are used with Varian High Dose Rate Afterloaders.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K073133